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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard S. Bein

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,604	Applicant(s) BEIN ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Remarks filed on 08/28/2009.

- Claims 1-24 have been cancelled.
- Claims 25-30 have been added.
- Claims 25-30 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-8, 10-16 and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite **are withdrawn** in view of cancellation of the claims.

However, upon further consideration a new ground(s) of rejection is prepared as follow.

2. Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from greater than 40 to 60 weight percent" of tantalum contrast agent is unclear. The phrase can read any where from 40 weight percent to 75, or 85 ... weight percent. Please clarify in order that one may readily ascertain what is the weight percentage of contrast agent is being claimed.

Claims 25-30 are vague and indefinite because it is unclear how the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent 0.07 or greater can arrive. With biocompatible polymer having lower limit from zero or one to 40 percent, it is impossible to arrive the recited ratio of 0.07. Please clarify in order that one may readily ascertain what is being claimed.

Claim Objections

3. Claims 26-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 26-30 are dependent on cancelled claim 24. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,4-8, 10-16 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339) in view of Paterson et al (US 2004/0224864) or Porter et al (US 2004/0197302) **are maintained** for reasons of record in the previous office action filed on 07/20/2009.

Applicant argues that Whalen patent fail to disclose the use of contrast agent in the amounts recited herein coupled with the ration of polymer to contrast agent.

This argument is not persuasive since Whalen patent teaches embolic composition comprising: a biocompatible polymer such as ethylene vinyl alcohol copolymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent (tantalum) at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent (dimethylsulfoxide) from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition (abstract and 0032-0035).

The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Furthermore, where close prior art exists, the normally definite term "about" can become indefinite, with Applicant bearing the burden of establishing that the term is sufficiently clear to avoid such art. See specifically Amgen v. Chugai, 927 F2d. 1200 (Fed. Cir. 1991), where the court found

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that the recitation of a specific activity of "about" 160,000 indefinite since it gave no hint as to which value between the prior art value of 128,620 and 160,000 constituted infringement. As noted at page 1218 of the decision, the holding was further supported by the fact that "nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term". That is the case here, nothing in the instant specification, prosecution history, or prior art provides any indication as to what range would be covered by the claimed term "about".

Accordingly, the values appear to overlap

Applicant argues that Whalen patent does not recite the inclusion of thixotropic agent in the embolic composition.

This argument is not persuasive since Whalen patent teaches embolic composition comprising biocompatible polymers including ethylene vinyl alcohol copolymers, hydrogels (e.g., acrylics), polyacrylonitrile which would read on thixotropic agents (0060). Whalen also teaches that biocompatible polymer preferably includes ethylene vinyl alcohol copolymer and adjustment of the viscosity of the composition can be readily achieved by merely adjusting the molecular weight of the polymer composition (0062) and composition has a viscosity of at least about 150 and more preferably at least about 200 cSt at 40°C.

Applicant also argues that both the Paterson et al ('864) and the Porter et al ('302) are unrelated art as compared to the Whalen patent.

This argument is not persuasive since this reference is combined for its teachings of knowledge in the art of embolic composition comprising biocompatible

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water-insoluble contrast agent from about 20 to 55 weight percent and composition can be applied advantageously to relatively viscous compositions used to embolize aneurysms as well as the lower viscosity of an AVM and the like. And also both Whalen and Paterson patent's teaches embolic composition having the viscosity of 150 cSt or 150 cP.

Double Patenting

Claims 25-30 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims of 1-6 of US Patent No. 5,667,767 ('767) and claims 1-8 and 16-23 of US Patent No. 5,695,480 ('480) **are maintained** for reasons of record in the previous office action filed on 07/20/2009.

Applicant argues that '767 patent fails to disclose high viscosity compositions such as those now claimed nor does it disclose the use of tantalum in excess of 40 weight percent in combination with a ratio of ethylene vinyl alcohol copolymer to tantalum of greater than 0.07 when using such high levels of tantalum.

This argument is not persuasive since '767 patent teaches embolizing composition comprising from about 10 to about 40 weight percent of water-insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate. The term "about 40 weight percent" would includes grater than about 40% and further the ration of biocompatible polymer to the water-insoluble biocompatible contrast agent is within the broad scope of 0.07 or greater when calculated with the recited amounts.

Applicant argues that '480 patent teaches polymers such as polyvinylacetate, cellulose acetate butyrate, nitrocellulose and copolymers of urethane/carbonate and styrene/maleate. As the now claimed invention is directed only to ethylene vinyl alcohol copolymers, any such recitation is not material to the now claimed invention.

This argument is not persuasive since '480 patent teaches biocompatible polymer is selected from the group consisting of cellulose acetates, ethylene vinyl alcohol copolymers, hydrogels ..., therefore recitation reads on composition comprising ethylene vinyl alcohol biocompatible polymer.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jagadishwar R Samala/

Examiner, Art Unit 1618

/Jake M. Vu/

Primary Examiner, Art Unit 1618